

6/29/05 4239-66903-02 393756.doc E-130-2002/0-US-03

PATENT

Attorney Reference Number 4239-66903-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Valenzuela *et al.*

Application No. 10/527,500

Filed: March 11, 2005

Confirmation No. 9994

For: P. ARIASI POLYPEPTIDES, P.  
PERNICIOSUS POLYPEPTIDES AND  
METHODS OF USE

Examiner: Not yet assigned

Art Unit: Not yet assigned

Attorney Reference No. 4239-66903-02

CERTIFICATE OF MAILING

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: MAIL STOP AMENDMENT, COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 on the date shown below.

Attorney or Agent  
for Applicant(s)

*Anne Carlson*

Date Mailed June 29, 2005

MAIL STOP AMENDMENT  
COMMISSIONER FOR PATENTS  
P.O. BOX 1450  
ALEXANDRIA, VA 22313-1450

TRANSMITTAL LETTER

Enclosed for filing in the application referenced above are the following:

- ☒ Supplemental Information Disclosure Statement
- ☒ Form 1449 and copies of references cited thereon (33)
- ☒ The Director is hereby authorized to charge any additional fees that may be required, or credit over-payment, to Deposit Account No. 02-4550. A copy of this sheet is enclosed.
- ☒ Please return the enclosed postcard to confirm that the items listed above have been received.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

By *Anne Carlson*  
Anne Carlson, Ph.D.  
Registration No. 47,472

One World Trade Center, Suite 1600  
121 S.W. Salmon Street  
Portland, Oregon 97204  
Telephone: (503) 226-7391  
Facsimile: (503) 228-9446

cc: Docketing

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re application of:** Valenzuela *et al.*

**Application No.** 10/527,500

**Filed:** March 11, 2005

**Confirmation No.** 9994

**For:** P. ARIASI POLYPEPTIDES, P.  
PERNICIOSUS POLYPEPTIDES AND  
METHODS OF USE

**Examiner:** Not yet assigned

**Art Unit:** Not yet assigned

**Attorney Reference No.** 4239-66903-02

CERTIFICATE OF MAILING

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: MAIL STOP AMENDMENT, COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 on the date shown below.

Attorney or Agent  
for Applicant(s)



Date Mailed June 29, 2005

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
PURSUANT TO 37 C.F.R. § 1.97(b)(3)**

MAIL STOP AMENDMENT  
COMMISSIONER FOR PATENTS  
P.O. BOX 1450  
ALEXANDRIA, VA 22313-1450


Listed on the accompanying form PTO-1449 and enclosed herewith are several English-language documents. Applicants respectfully request that these documents be listed as references cited on the issued patent.

Applicants filed this Information Disclosure Statement ("IDS") before the mailing date of a first Office action on the merits. As a result, no fee should be required to file this IDS. However, if the Patent Office determines that a fee is required for Applicants to file this IDS, authorization to charge any such fees to Deposit Account No. 02-4550 is provided on the accompanying transmittal letter.

The filing of this IDS shall not be construed to be an admission that the information cited in the statement is, or is considered to be, prior art or otherwise material to patentability as defined in 37 C.F.R. §1.56.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

By 

Anne Carlson, Ph.D.

Registration No. 47,472

One World Trade Center, Suite 1600  
121 S.W. Salmon Street  
Portland, Oregon 97204  
Telephone: (503) 226-7391  
Facsimile: (503) 228-9446

<b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Attorney Docket Number	4239-66903-02
	Application Number	10/527,500
	Filing Date	March 11, 2005
	First Named Inventor	Valenzuela
	Art Unit	Not yet assigned
	Examiner Name	Not yet assigned

### FOREIGN PATENT DOCUMENTS

Examiner's Initials*	Cite No. (optional)	Country	Number	Publication Date	Name of Applicant or Patentee
		WIPO/PCT	WO 95/06729	9 March 1995	Matlashewski <i>et al.</i>
		WIPO/PCT	WO 02/102324	27 Dec 2002	Valenzuela <i>et al.</i>
		WIPO/PCT	WO 2004/039958	13 May 2004	Valenzuela <i>et al.</i>

### OTHER DOCUMENTS

Examiner's Initials*	Cite No. (optional)	
		ADLER <i>et al.</i> , "The mouthparts, alimentary tract and salivary apparatus of the female <i>Phlebotomus papatasi</i> ," <i>Ann. Trop. Med. Parasitol.</i> 20:109, 1926.
		BELKAID <i>et al.</i> , "A natural model of <i>Leishmania major</i> infection reveals a prolonged "silent" phase of parasite amplification in the skin before the onset of lesion formation and immunity," <i>J. Immunol.</i> 165:969-977, 2000.
		CHARLAB <i>et al.</i> , "Toward an understanding of the biochemical and pharmacological complexity of the saliva of a hematophagous sand fly <i>Lutzomyia longipalpis</i> ," <i>Proc. Natl. Acad. Sci., USA.</i> 96(26):15155-15160, 1999
		HASKÓ <i>et al.</i> , "Adenosine receptor agonists differentially regulate IL-10, TNF-alpha, and nitric oxide production in RAW 264.7 macrophages and in endotoxemic mice," <i>J. Immunol.</i> , 157(10):4634-4640, 1996
		HASKÓ <i>et al.</i> , "Adenosine inhibits IL-12 and TNF-[alpha] production via adenosine A2a receptor-dependent and independent mechanisms," <i>FASEB J.</i> , 14(13):2065-2074, 2000
		GURUNATHAN <i>et al.</i> , "Vaccination with DNA encoding the immunodominant LACK parasite antigen confers protective immunity to mice infected with <i>Leishmania major</i> ," <i>J. Exp. Med.</i> 186:1137-1147, 1997.
		GURUNATHAN <i>et al.</i> , "Vaccine requirements for sustained cellular immunity to an intracellular parasitic infection," <i>Nat. Med.</i> 4:1409-1415, 1998.
		KAMHAWI <i>et al.</i> , "Protection against cutaneous leishmaniasis resulting from bites of uninfected sand flies," <i>Science</i> 290:1351-1354, 2000.
		KATZ <i>et al.</i> , "Adenosine, AMP, and protein phosphatase activity in sand fly saliva," <i>Am. J. Trop. Med. Hyg.</i> 62:145-150, 2000.

EXAMINER SIGNATURE:	DATE CONSIDERED:
* Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.	

<b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Attorney Docket Number	4239-66903-02
		Application Number	10/527,500
		Filing Date	March 11, 2005
		First Named Inventor	Valenzuela
		Art Unit	Not yet assigned
		Examiner Name	Not yet assigned
Examiner's Initials*	Cite No. (optional)	<b>OTHER DOCUMENTS</b>	
		KILLICK-KENDRICK, Biology of <i>Leishmania</i> in phlebotomine sand flies. In Biology of the Kinetoplastida. W. Lumsden and D. Evans, editors. Academic Press, New York. 395, 1979	
		LERNER <i>et al.</i> , "Isolation of maxadilan, a potent vasodilatory peptide from the salivary glands of the sand fly <i>Lutzomyia longipalpis</i> ," <i>J. Biol. Chem.</i> , 266(17):11234-11236, 1991	
		MAKOUL <i>et al.</i> , "Prostaglandin E2 inhibits the activation of cloned T cell hybridomas," <i>J. Immunol.</i> , 134(4):2645-2650, 1985	
		MELLANBY, "Man's Reaction to Mosquito Bites," <i>Nature</i> 158(4016):554-555, 1946	
		MÉNDEZ <i>et al.</i> , "The potency and durability of DNA- and protein-based vaccines against <i>Leishmania major</i> evaluated using low dose, intradermal challenge," <i>J. Immunol.</i> 166(8):5122-5128, 2001.	
		MODI <i>et al.</i> , "A simple technique for mass rearing <i>Lutzomyia longipalpis</i> and <i>Phlebotomus papatasi</i> (Diptera: Psychodidae) in the laboratory," <i>J. Med. Ent.</i> 20:568-569, 1983.	
		NONG <i>et al.</i> , "Peptides encoded by the calcitonin gene inhibit macrophage function," <i>J. Immunol.</i> , 143(1):45-49, 1989	
		QURESHI <i>et al.</i> , "Immunomodulatory properties of maxadilan, the vasodilator peptide from sand fly salivary gland extracts," <i>Am. J. Trop. Med. Hyg.</i> , 54(6):665-671, 1996	
		RIBEIRO <i>et al.</i> , "Blood-finding strategy of a capillary-feeding sandfly, <i>Lutzomyia longipalpis</i> ," <i>Comp. Biochem. Physiol.</i> , 83(4):683-686, 1986	
		RIBEIRO <i>et al.</i> , "Salivary apyrase activity of some Old World phlebotomine sand flies," <i>Insect Biochem.</i> 19:409-412, 1989.	
		RIBEIRO <i>et al.</i> , "Salivary glands of the sand fly <i>Phlebotomus papatasi</i> contain pharmacologically active amounts of adenosine and 5'-AMP," <i>J. Exp. Biol.</i> , 202(Pt. 11):1551-1559, 1999	
		SANTOLI <i>et al.</i> , "Prostaglandin E precursor fatty acids inhibit human IL-2 production by a prostaglandin E-independent mechanism," and Zurier, <i>J. Immunol.</i> , 143(4):1303-1309, 1989	
		SJÖLANDER <i>et al.</i> , "Induction of a Th1 immune response and simultaneous lack of activation of a Th2 response are required for generation of immunity to leishmaniasis," <i>J. Immunol.</i> 160:3949-3957, 1998.	
EXAMINER SIGNATURE:		DATE CONSIDERED:	
* Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.			

<b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Attorney Docket Number	4239-66903-02
		Application Number	10/527,500
		Filing Date	March 11, 2005
		First Named Inventor	Valenzuela
		Art Unit	Not yet assigned
		Examiner Name	Not yet assigned
<b>Examiner's Initials*</b>	<b>Cite No. (optional)</b>	<b>OTHER DOCUMENTS</b>	
		SMELT <i>et al.</i> , "B cell-deficient mice are highly resistant to <i>Leishmania donovani</i> infection, but develop neutrophil-mediated tissue pathology," <i>J. Immunol.</i> 164:3681-3688, 2000.	
		SOARES <i>et al.</i> , "The vasoactive peptide maxadilan from sand fly saliva inhibits TNF-alpha and induces IL-6 by mouse macrophages through interaction with the pituitary adenylate cyclase-activating polypeptide (PACAP) receptor," <i>J. Immunol.</i> 160:1811-1816, 1998	
		STOCKMAN <i>et al.</i> , "The effect of prostaglandins on the in vitro blastogenic response of human peripheral blood lymphocytes," <i>Exp. Hematol.</i> , 2(2):65-72, 1974	
		THEODOS <i>et al.</i> , "Analysis of enhancing effect of sand fly saliva on <i>Leishmania</i> infection in mice," <i>Infect. Immun.</i> 59:1592-1598, 1991.	
		TITUS <i>et al.</i> , "The role of vector saliva in transmission of arthropod-borne disease," <i>Parasitology Today</i> 6(5):157-160, 1990.	
		VALENZUELA <i>et al.</i> , "The salivary apyrase of the blood-sucking sand fly <i>Phlebotomus papatasi</i> belongs to the novel Cimex family of apyrases," <i>J. Experimental Biology</i> , 204:229-237, 2001.	
		WEBSTER, "Role of purines in lymphocyte function," <i>Asian Pac. J. Allergy Immunol.</i> , 2(2):311-317, 1984	
		XU <i>et al.</i> , "Protection against leishmaniasis by injection of DNA encoding a major surface glycoprotein, gp63, of <i>L. major</i> ," <i>Immunology</i> 84:173-176, 1995.	

EXAMINER SIGNATURE:	DATE CONSIDERED:
<p>* Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	